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TITLE: Investigating clinical benefits of a novel sleep-focused mind-body program on Gulf War Illness (GWI) symptoms: An exploratory randomized controlled trial

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13. SUPPLEMENTARY NOTES

14. ABSTRACT

Subjects are being recruited for the proposed study and the study is still ongoing during the project extension period approved by DoD. There is no finding to report from the study as of 30/06/2014.

15. SUBJECT TERMS
mind-body intervention, awareness training, mindfulness, insomnia, sleep disturbance, Gulf War Illness

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Annual Report

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Introduction

The purpose of this study is to conduct an exploratory randomized controlled trial designed to evaluate clinical benefits of a novel mind-body intervention program for primary care management of Gulf War Veterans with sleep disturbance and unrelieved GWI symptoms. The main objective of the study is to evaluate and compare the clinical benefit of two sleep-focused therapeutic interventions: Mind-Body Bridging (MBB) and Supportive Education (SED) on sleep and co-morbid Gulf War related symptoms. MBB consists of cognitive and attentional (experiential) techniques for cultivating present-focused, non-judgmental awareness of one's body, emotions, and thoughts. We will recruit 72 Gulf War veterans, who first will undergo a comprehensive screening assessment and then will be assigned to one of the two programs (MBB or SED). Each Veteran will receive a total of 6 hours of treatment, in 2-hour sessions once a week over 3 consecutive weeks. Each Veteran will be evaluated again after treatment has ended. Three months after treatment ends, Veterans will complete follow-up questionnaires. These assessments will help us to evaluate both the efficacy of the intervention programs and any differences in individual treatment response. Additionally, the project will explore underlying mechanisms of action involved in treatment benefits resulting from MBB and SED by using a biomarker of stress as a proxy indicator of intermediate mechanisms activated by MBB and SED.

Body

Progress reported in this Annual Report (please see below) is consistent with Milestone 2 specified in SOW during Year 3. We requested no-cost extension of the project and obtained approval to extend the project to February 2015. With respect to Milestone 2 specified in SOW, we have continued to recruit Gulf War 1 Veterans who have self-reported sleep disturbance and to conduct screening sessions. During Year 3 period, eligible veterans who completed screening were assigned to the intervention groups and they also completed pre- and post-intervention assessments as well as 3-month follow-up assessment. We are continuing our recruiting and screening effort and we will run two groups (one group for MBB and one group for control) in August 2014.

Key Research Accomplishments (as of the end of June 2014)

- 54 Veterans consented to participated in the study
- 38 Veterans completed intervention sessions
- 37 Veterans completed post-intervention evaluation
- 28 Veterans completed 3 month follow-up evaluation

Reportable Outcomes……

Study enrollment is still currently ongoing and we do not have any result yet to report here.

Conclusion

As we will continue to recruit eligible GW1 Veterans into the ongoing study during the extension period, we are optimistic that we will be able to recruit enough GW Veterans into our study. Given this, we are currently not in a position to reach any conclusion regarding study aims and hypothesized benefits of the experimental intervention program (MBB) at the end of Year 3.

References

None

Appendices

None

Supporting Data

None